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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,392	07/10/2002	Wolf-Dieter Deckwer	930008-2069	4954

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EXAMINER	
PATTERSON, CHARLES L JR	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,392	DECKWER ET AL.	
	Examiner	Art Unit	
	Charles L. Patterson, Jr.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *16 and 17* is/are allowed.

6)☒ Claim(s) *1-15 and 18-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The disclosure is objected to because of the following informalities:

Applicants amended the first full paragraph on page 13 by changing "GIuC" to "GluC", but did not indicated what "GluC" is. The examiner does not know what "GluC" is nor the significance of this. In addition, 37 CFR § 1.121 requires that amendment be made by adding or deleting a paragraph, an entire section or by a substitute specification. Applicant has only changed one sentence, which does not meet the rule.

Appropriate correction is required.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 is confusing because it depend from claim 28 but contains only the limitations of claim 28. It therefore does not conform to 35 USC § 112 fourth paragraph in that is does not further limit claim 28.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-6 and 20-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is

repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

As stated previously, claim 5 is are drawn to "a mutant or derivative of SEQ ID NO:1 resulting from substitution...insertion...or deletion of amino acids from SEQ ID NO:1, and wherein said mutant or derivative has ester-group-cleaving enzyme activity" and "a part of the sequence". New claims 26-32 are drawn to the "ester-group-cleaving enzyme" of claim 5 or the "synthetic peptide" of claim 6 and an additional component and a "method of degradation of an ester-group-containing macromolecule" by using the synthetic protein of claim 6, which contains the limitation of "a part of the sequence". Applicants argue that "the regions of the claimed protein required for ester group cleaving activity were well known to one of skill in the art" as evidenced by Perez, et al. (AR), which is stated as showing in Figure 3 the "conserved region of the active site of the claimed protein". Figure 3 show the sequence of a lipase from *Streptomyces lividans* with five amino acids indicated as "surrounding the active site Ser" (emphasis in original). This is a different enzyme from a different source having a different sequence, and possibly having a different activity, from the enzyme of the instant claims. It is well known by one of ordinary skill in the art that even a change of one amino acid can affect the activity of an enzyme. The instant specification does not teach which residues to substitute, insert or delete from SEQ ID NO:1 and obtain an enzyme still having activity. It is pointed out that the instant language reads on another completely different enzyme as all of the amino acids can be substituted. Therefore it is maintained that one of ordinary skill in the art is not taught by the instant specification what amino acids to substitute, insert or delete from SEQ ID NO:1 and obtain an enzyme with "ester-group-cleaving" activity. The specification further does

not teach the ordinary artisan to make a peptide having "a part of" SEQ ID NO:1 and still having activity.

The previous rejection of claims 7-9 and 16-17 under 35 USC § 112 first paragraph is hereby dropped in view of applicants' arguments.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 102(a or e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over either of Kellis, et al. (A), Kleeberg, et al. (V) or Bachmann, et al. (X). This rejection is repeated for essentially the reasons given in the last action. Ap-

plicants arguments have been carefully considered but do not overcome the instant rejection.

Applicants argue that Kellis "does not specifically teach *Thermomonospora* enzymes cleaving polyesters" and that "only one enzyme...shows activity for polyethylene terephthalate (PET)". It is pointed out that the instant claims do not require that the enzyme cleave polyesters not PET, but simply that the enzyme be an "ester-group-cleaving enzyme". It is further argued that the enzyme taught by Kleeberg, et al. has different characteristics that the enzyme taught by the instant specification. It is pointed out that the instant claims are not limited to the specific enzyme taught by the specification.

New reference Bachmann, et al. teaches the isolation and purification of xylanases, endoxylanases, α-arabinofuranosidases and acetyl esterases from *Thermononospora fusca*. These are all "ester-group-cleaving" enzymes. It is maintained that these enzymes are the same as the enzymes of the instant claims, absent very convincing proof to the contrary.

Claims 1-6, 10-15, 18-19 and 26-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Kellis, et al. (A), Kleeberg, et al. (V) or Bachmann, et al. (X). The references have been characterize *supra*. It is maintained that it would have been obvious to add other components, including enzymes, to the ester-group-cleaving enzyme, to purify the enzyme by well known and used methods and to use the enzyme to degrade ester-group-containing compounds, absent unexpected results. The motivation would have been to determine the interaction of the enzyme with other components or enzymes, to further purify the enzyme and to use the enzyme for its intended use.

Claims 1-15 and 18-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Kellis, et al. (A), Kleeberg, et al. (V) or Bachmann, et al. (X) in view of Goldwasser, et al (B). This rejection is repeated for essentially the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

The primary references have been characterized *supra*. Applicants argue that the primary references do not teach the enzyme of the instant claims and therefore it would not have been obvious to make antibodies against them. This argument have been addressed *supra*.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose

telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
January 18, 2005